K113329

JAN 17 2012

510(k) Summary
for the
K2M Cervical Plate System, Modifications

This safety and effectiveness summary for the Pyrenees Cervical Plate System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
K2M, Inc.
751 Miller Drive SE,
Leesburg, VA 20175

Contact Person :
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751 Miller Drive SE
Leesburg, VA 20175
Telephone: 703-777-3155

Date Prepared: November 11, 2011

2. Tradename: K2M Cervical Plate System 510(k), Modifications
Common Name: Spinal Fixation System
Classification Name: Spinal Intervertebral Body Fixation Orthosis (888.3060)
Product Code: KWQ
Device Class: II

3. Predicate or legally marketed devices which are substantially equivalent :

- Pyrenees Cervical Plate System (K2M, Inc.) K063544
- Amendia Cervical Plate System, K100265

4. Description of the device :

The K2M Cervical Plate System is a spinal fixation system which consists of cervical screws and plates. All of the components are available in a variety of sizes to match more closely the patient's anatomy.

Materials: The devices are manufactured from titanium alloy and nitinol, per ASTM and ISO standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of cervical segments of the spine.

5. Intended Use:

K2M Cervical Plate Systems are indicated for use in anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions (pseudarthrosis) and deformity (defined as scoliosis, kyphosis or lordosis).

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The design features and sizing of the components were compared to predicate devices and the Pyrenees Cervical Plate System implants were found to be substantially the same as these devices. They are manufactured from the same materials (in accordance with ASTM F136 and ASTM F2063) and present with the same intended uses as these systems.

There are no significant differences between the K2M Cervical Plate System and other systems currently being marketed. The K2M plates are substantially equivalent to these other devices in design, function, material and intended use.

7. Comparison of the performance characteristics of the device to predicate and legally marketed devices :

The K2M Cervical Plate System was mechanically tested and compared to the predicate systems and other currently marketed systems. The K2M implants performed equally to, or better than, these systems in static compression, static torsion and dynamic compression testing per ASTM F1717.

Therefore, the performance of the K2M Cervical Plate System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 17 2012

K2M, Inc.
% Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive SE, Suite F1
Leesburg, Virginia 20175

Re: K113329
Trade/Device Name: K2M Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 20, 2011
Received: December 21, 2011

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113329

Indications for Use

510(k) Number: Pending

Device Name: K2M Cervical Plate System, Modifications

Indications for Use:

The K2M Cervical Plate Systems are indicated for use in anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (including fractures), spinal stenosis and tumors (primary and metastatic), failed previous fusions (pseudarthrosis) and deformity (defined as scoliosis, kyphosis or lordosis).

Prescription Use X___ AND/OR Over-the-counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113329